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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,838	10/15/2001	Ornella Flore		1712

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EXAMINER

HENRY, MICHAEL C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/976,838	<b>Applicant(s)</b> FLORE, ORNELLA	
	<b>Examiner</b> Michael C. Henry	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11,13,15,17,19,21,23,25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11,13,15,17,19,21,23,25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 08/21/06.

The amendment filed 08/21/06 affects the application, 09/976,838 as follows:

1. Claims 12, 14, 16, 18, 20, 22, 24, 26, 28 have been canceled. Upon further consideration the examiner has determined that the indicated allowable subject matter of the prior office action is not appropriate. Consequently, the said allowable subject matter is withdrawn.
2. The responsive to applicants' arguments is contained herein below.

Claims 11, 13, 15, 17, 19, 21, 23, 25, 27 are pending in the application

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13, 15, 17, 19, 21, 23, 25, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozuka et al. (JP 05306228) in view of Takeda et al. (J Pharm Pharmacol. 1996 Sep; 48 (9): 902-905).

In claim 11, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to a patient a therapeutic amount of glycyrrhizic acid wherein the glycyrrhizic acid inhibits the transcription of viral latent genes of the Epstein Barr virus. Claims 13, 15, 17, 19, 21, 23, 25 are drawn to the method of claim 11 involving the use of different dosages, routes of administration and a salt of glycyrrhizic acid. Claim 27 is drawn to a method of treating

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Epstein Barr comprising the steps of administering to a patient a therapeutic amount of glycyrrhizic acid wherein the glycyrrhizic acid inhibits the expression of latent viral antigens of the Epstein Barr virus.

Kozuka et al. disclose a method of treating Epstein-Barr virus early antigen comprising inhibiting the formation of Epstein-Barr virus by administering a derivative of a triterpenoid acid containing a moiety of glycyrrhetic acid (glycyrrhetic acid monoglucuronide or its salt) (see abstract).

The difference between applicant's claimed method and the method of Kozuka et al. is that applicant uses glycyrrhizic acid whereas Kozuka et al. uses glycyrrhetic acid monoglucuronide. Furthermore, it should be noted that glycyrrhetic acid (also called glycyrrhetic acid) is the aglycone of the glycyrrhetic acid monoglucuronide used by Kozuka et al., and glycyrrhetic acid (glycyrrhetic acid) is the active component of glycyrrhetic acid monoglucuronide.

Takeda et al. disclose that upon oral administration of a therapeutic dose of glycyrrhizic acid to rats, glycyrrhizic acid is converted to the active ingredient, glycyrrhetic acid (glycyrrhetic acid) (see abstract).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the process of Kozuka et al. to treat Epstein Barr virus by administering glycyrrhizic acid to a patient, since Takeda et al. disclose that glycyrrhizic acid is converted to the active ingredient, glycyrrhetic acid (glycyrrhetic acid) in vivo.

One having ordinary skill in the art would have been motivated, to use the process of Kozuka et al. to treat Epstein Barr virus by administering glycyrrhizic acid to a patient, since

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Takeda et al. disclose that glycyrrhizic acid is converted to the active ingredient, glycyrrhetic acid (glycyrrhetic acid) in vivo. It should be noted that the use of specific dosages and the routes of administration depend on factors such as the severity of the disease or condition, the age, weight and kind of the patient treated, and is well within the purview of a skilled artisan.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13, 15, 17, 19, 21, 23, 25, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanborm (US 4,891,221).

In claim 11, applicant claims a method of treating Epstein Barr virus comprising the steps of administering to a patient a therapeutic amount of glycyrrhizic acid wherein the glycyrrhizic acid inhibits the transcription of viral latent genes of the Epstein Barr virus. Claims 13, 15, 17, 19, 21, 23, 25 are drawn to the method of claim 11 involving the use of different dosages, routes of administration and a salt of glycyrrhizic acid. Claim 27 is drawn to a method of treating Epstein Barr comprising the steps of administering to a patient a therapeutic amount of glycyrrhizic acid wherein the glycyrrhizic acid inhibits the expression of latent viral antigens of the Epstein Barr virus.

Shanborm discloses that glycyrrhizic acid triterpenoids (GTPDs) including glycyrrhizic acid can be used to treat Epstein-Barr virus (see col. 5, lines 38-48). Furthermore, Shanborm discloses that glycyrrhizic acid is an exemplary GTPD (see col. 4, lines 11-41). It should be noted

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that the examiner considers the inhibition of transcription of viral latent genes or the inhibition of the expression of latent viral antigens an effect, mechanism, or mode of action by which said treatment of Epstein Barr occurs.

Shanborm fails to exemplify the use of glycyrrhizic acid to treat Epstein-Barr virus but suggest that it can be used.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to treat Epstein Barr virus with any GTPD such as the glycyrrhizic acid suggested by Shanborm by administering said glycyrrhizic acid to a patient and to use different dosages and routes of administration, depending on factors such as the severity of the Epstein Barr virus, the age, weight and kind of the patient treated.

One having ordinary skill in the art would have been motivated, to treat Epstein Barr virus with any GTPD such as the glycyrrhizic acid suggested by Shanborm by administering said glycyrrhizic acid to a patient and to use different dosages and routes of administration, depending on factors such as the severity of the Epstein Barr virus, the age, weight and kind of the patient treated.

#### ***Response to Amendment***

Applicant's arguments with respect to claims 11, 13, 15, 17, 19, 21, 23, 25, 27 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

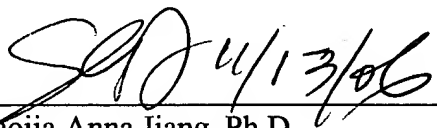
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

  
Shaojia Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1623

November 11, 2006.